REMARKS/ARGUMENTS

There are now 22 claims pending.

Claim 1 has been amended to specify that the corneal implant comprises a "hydrated" membrane and that the membrane comprises "a mixture of" a biological polymer and a polyacrylamide. Support for the feature "hydrated" membrane may be found in the description, for example, at page 14, line 22 to page 15, line 2, and page 16, lines 22 to 29. Support for "a mixture of" a biological polymer and a polyacrylamide may be found throughout the specification and in particular, Examples 1 to 3 spanning pages 16 to 18.

Claim 4 has been amended to better define the scope of protection sought by the Applicant. More specifically, the members "glycoprotein, peptide, glycosaminoglycan" have been removed from the Markush group of biological polymers. Furthermore, new dependent claims 31 and 33 have been added to define bioactive compounds that may be included in the biological polymer/polacrylamide mixture and in the hydration solution, respectively.

New claims 28 to 30 and 32 have been added which are directed to other aspects of the invention that are supported by the specification as originally filed. Examples of where support may be found for the new claims are itemized below:

Claims	Support
28	Claim 27 and page 16, lines 22 to 29
29	Page 13, lines 12 to 15 Page 21, Table II
30 to 33	Page 5, lines 14 to 24 Page 14, lines 3 to 10 Page 19, Example 5

It is believe that no new subject matter has been added by way of this amendment.

The Examiner confirms Applicant's election of the claims of Group I (claims 1 to 15 and 25 to 27) directed to the corneal implant, and election of the Polyacrylamide: Species A (poly(N-alkylacrylamide)) and Collagen: Species A (telocollagen or atelocollagen).

Claims 6 and 7 have been withdrawn and claims 16 to 24 have been cancelled without prejudice or disclaimer. Applicant reserves the right to prosecute the subject matter of the cancelled claims in one or more divisional applications.

Specification

In response to the Examiner's requisition, the abstract has been amended to replace "ppolymer" with --polymer--.

The Applicant has also taken the opportunity to correct a few minor grammatical and typographical errors in the description. No new subject matter has been added in respect of the overall revisions effected therein.

Drawings

The Examiner has objected to the drawings under 37 CFR 1.83(a) on the grounds that the "plurality of membranes" recited in claim 15 must be shown, or the features canceled from the claim. Applicant respectfully disagrees.

Under U.S. patent law and practice, an applicant is required to furnish a drawing where necessary for the understanding of the subject matter to be patented. Generally, the role of the drawings is to clarify the principles of the construction of a device, which is often required in the case of mechanical inventions. Accordingly, those inventions which need to be illustrated by means of drawings must be so illustrated in an application for a patent. This is not the case according to the instant invention, which can be readily envisioned by a skilled person based on the description of the invention provided in the application. For example, at page 6, lines 16 to 23, page 7, lines 20 to 25 and page 12, lines 20 to 25 of the description, a skilled person would readily understand that a "plurality of membranes" is essentially two or more membranes of the instant invention, one layered on top of the other, i.e. multilayered membrane. As such, no further clarification by way of a drawing to illustrate this fundamental concept is required.

Accordingly, Applicant respectfully submits that the instant application satisfies 37 CFR 1.83(a) and in this respect, requests that the objection be withdrawn.

35 USC §112, 2nd paragraph – Claims 25 and 26

The objection to Claim 25 has been addressed by replacing the expression "to said subject" at page 32, line 16, with --to a subject-- to provide a proper antecedent basis for claim 26.

35 USC §102(b) – Claims 1, 4, 5, 8, 10, 13, 14, 25 and 26

The Examiner has applied Perez *et al.* (WO 94/17851) and Graham *et al.* (US 5,433,745) alleging that certain of the claims lack novelty in view of one or the other of these references.

Claim 1 has been amended to specify that the corneal implant membrane comprises "a mixture of a biological polymer and a polyacrylamide". Claims 4, 5, 8, 10 to 14, 25 and 26, by virtue of their dependency on claim 1, are similarly amended.

Applicant respectfully submits that claims 1, 4, 5, 8, 10 to 14, 25 and 26, as presently amended, patentably distinguish over Perez *et al.* and Graham *et al.*

MPEP §2131 provides that:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The **identical invention** must be shown in as complete detail as contained in the ... claim." [Emphasis added.] *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim.

Perez *et al.* describe a "two-layer" composite material composed of a hydrogel and a thin layer of corneal tissue or collagen matrix. They hydrogel is directly covalently attached to the collagen matrix, or an intermediate material is used to adhere the hydrogel and the collagen matrix together.

Graham *et al.* also describe a "two-layer" corneal implant comprising a lens body comprising a core having an outer surface made of a hydrogel composition containing water and a hydrophilic polymeric material. A coating of a synthetic polymeric material is located on the outer surface of the core and covalently bonded to the hydrogel composition.

Neither Perez *et al.* nor Graham *et al.* disclose a corneal implant comprising a membrane comprising a "mixture" of a biological polymer and a polyacrylamide.

Accordingly, Applicant respectfully submits that the instant invention is novel and patentably distinguishable over the prior art and in this respect, requests that the rejections be withdrawn.

35 USC §103(a) - Claims 2, 3, 8, 9, 13 to 15 and 27

The Examiner has applied Perez *et al.* and Graham *et al.* in combination with Takezawa *et al.* alleging that the subject matter of claims 2 and 3 is obvious in light of these references. On the same grounds, claims 9, 15 and 27 have been rejected in view of Perez *et al.* and claims 8, 9, 13 to 15 and 27 have been rejected in view of Graham *et al.*

As discussed above (see (102(b) rejection), claim 1, and dependent claims thereto, have been amended to specify that the corneal implant membrane comprises a "mixture" of a biological polymer and a polyacrylamide and that the membrane is "hydrated".

The references Perez *et al.* and Graham et al. are described above (see 102(b) rejection). In essence, both references describe a "two-layer" composite material composed of a hydrogel composition covalently bonded to a collagen matrix and a synthetic polymeric material, respectively. Neither Perez *et al.* nor Graham *et al.* disclose a corneal implant comprising a membrane wherein the membrane comprises a mixture of a biological polymer and a polyacrylamide.

Takezawa *et al.* disclose a "cell culture substrate" for the purpose of achieving cell proliferation and detachment without using detachment agents, e.g. trypsin, that could otherwise damage cellular function. In order to detach the cells, the temperature of the substrate is lowered below the lower critical solubility temperature (LCST). In this respect, Applicant submits that the prior art reference relates to a non-analogous field compared to that of the claimed invention and

therefore is not pertinent to the particular problem with which the inventor was involved. The problem in the instant case was to produce an artificial cornea from biocompatible materials that can support cell growth without cytotoxicity effects while avoiding any chemical reactions that could impair cell viability and the healing process when implanted in a subject. The artificial implant has to also be optically clear (not opaque) and easy for the surgeon to manipulate/handle at room temperature. Accordingly, a person interested in fabricating an artificial cornea implant would not look for guidance in the field of cell culture substrates. Furthermore, there is no suggestion or motivation in the prior art for combining or modifying the references to arrive at the corneal implant, as claimed.

Applicant respectfully submits that a *prima facie* case of obviousness cannot be established if there is no basis or suggestion in the art for combining or modifying the references, or the cited art is non-analogous to the claimed invention.

Accordingly, Applicant submits that the instant invention is inventive and patentably distinguishable over the prior art and in this respect, requests that the rejections be withdrawn.

In view of the forgoing, early favorable consideration of this application is earnestly solicited.

It is believed this responds to all of the Examiner's concerns, however if the Examiner has any further questions, she is invited to contact Elizabeth A. Hayes-Quebec (Reg. No. 48,305) at 613-232-2486. Further, If the Examiner does not consider that the application is in a form for allowance, an interview with the Examiner is respectfully requested.

Respectfully submitted,

CHARLES J. DOILLON, ET AL.

By _____

Ralph A. Dowell
Reg. No. 26,868
Tel.: (703) 415-2555
Fax: (703) 415-2559

Date: March 21, 2006

EAH:pw

Correspondence address 000293
Dowell & Dowell, P.C.
Suite 406
2111 Eisenhower Ave.
Alexandria, VA 22314
U.S.A.

(703) 415-2555